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PATENT & TRADEMARK OFFICE

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Nicole BARIE et al. Group Art Unit: 1641

Serial No.: 09/694,241 Examiner: Kartic Padmanabhan

Filed: October 23, 2000

For: DEXTRAN-COATED SURFACE

REQUEST FOR RECONSIDERATION

Mail Stop Non-Fee
Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Applicants request reconsideration of the rejections in the Office Action mailed February 23, 2004 in view of the following remarks.

Claims 3 and 6 to 15 (all the claims in the case) were rejected under the first paragraph of 35 USC 112 as allegedly based upon a non-enabling disclosure. The Examiner states that there is no mention in the specification of a TRIMID modified aminodextran and thus "there is a clear lack of direction or guidance" in using same for the present invention. Applicants respectfully submit

that the application is properly enabling. The Examiner is directed to original claims 3 and 4, which specifically disclose as part of the original application a TRIMID-modified aminodextran. Thus there is specific reference to the material in the application as filed. (An original claim is "by elementary principles of patent law, ... considered as a part of the original disclosure." In re Anderson, 176 USPQ 331, 332 (CCPA 1973)). While the working example in the case (as well as Fig. 1) shows T-BSA rather than T-aminodextran, applicants say that one of ordinary skill in the art would have no difficulty in substituting one protein for another for use in the present invention. Indeed, the Examiner takes such a position in his attempt to justify the art rejections; see the statements in the most recent Office Action on page 5, lines 3 to 6 and page 6, lines 5 to 8.

It is further asserted that the specification does not enable one "to make and use the invention commensurate in scope with these claims." The claims are specific to the type of TRIMID-modified protein used in the invention; claim 3, the only independent claim, calls for TRIMID-modified aminodextran. Applicants say that the

specification more than adequately teaches making and using an invention of such scope.

Applicants respectfully disagree with the statement in the Office Action that "extraordinary skills and undue experimentation would be required to make and use the invention." As indicated above, the specification as filed clearly shows the use of T-BSA and T-aminodextran. BSA is a polymer of different amino acids, whose lycene residues carry amino acids; it is those amino groups that are derivatized with TRIMID to form T-BSA depicted in Fig. 1. Aminodextran is a polymer consisting of glucose monomers, some of which contain amino groups. The person of ordinary skill in the art would have no difficulty in accepting readily and understanding easily that the same type of reactions can take place on the amino groups of these two polymers. Enclosed for the Examiner's consideration and review are pages from a 2003 issue of Analytical Chemistry discussing the formation of surface acoustic wave biosensors using a polymer such as aminodextran; see the discussion in the paragraph bridging the columns on page 5562 and the paragraph bridging the columns on page 5563. The Examiner is referred to the footnoted articles in the enclosure which establish

that at the time of the present invention the person of ordinary skill in the art would have no difficulty in practicing the subject matter claimed. Applicants emphasize that they are not relying on the 2003 publication itself to show that the specification is enabling. Applicants are relying upon the publication to establish that the state of the art at the time of the invention was such that the ordinarily skilled persons could practice the invention. The rejection should be withdrawn.

Should the rejection be maintained, the Examiner is asked to indicate on the record what is lacking in the specification and the background art that would not allow the routineer to practice the invention.

The rejection of claims 3, 6, and 11 under 35 USC 103 as unpatentable over Swan et al. '056 or Hubbell et al. '914 in view of Chai-Gao et al. '802 is respectfully traversed.

The claimed subject matter is directed to a dextran-coated surface formed in a manner represented by instant Fig. 1. There one can see a substrate, more particularly, a polyimide having dextran attached thereto through the intermediary of a TRIMID-modified protein; in the figure, the protein is BSA making the

intermediary T-BSA. The present claims call for TRMID-modified aminodextran, which is used in the same manner as the T-BSA in Fig. 1; see the previous comments rebutting the 35 USC 112, first paragraph rejection. Applicants respectfully submit that the references in combination do not teach or suggest the invention claimed herein. Indeed, applicants again respectfully submit that the references are improperly combined and that no prima facie case of obviousness has been made out.

Swan et al. '056 without question is directed to various crosslinked matrices having covalently immobilized chemical species and unbound releasable chemical species to provide release of one of those chemical species from the matrix. The matrix is a three-dimensional one so it may achieve the intended purposes of the Swan et al. '056 invention. The matrix is not a conventional substrate as depicted in applicants' Fig. 1. The matrix of the reference is a self-contained unit; see, for example, the last sentence of the Abstract and column 8, lines 56 to 65. The Examiner remarked in the Advisory Action mailed September 29, 2003 that "such [a conventional substrate] is not required in the claims." While the claims do not use the term "conventional substrate," applicants

point out that the argument was made to point out substantial differences between what is claimed and what this reference teaches or suggests. The person of ordinary skill in the art would not be lead to the present invention from a reading of Swan et al. '056. The invention of Swan et al. '056 is not the invention claimed here. See the additional comments below.

The reference discloses as an example of the first or second chemical species (which may also be regarded as the immobilized (bound) or unbound species) dextran sulfate (see the next-to-last subparagraph of patent claim 12) and lists various materials including organic polymers (see the last subparagraph of patent claim 12) as coupling compounds. There is no disclosure in the reference of the use of a protein, modified or not, as a coupling compound and there is no mention in the reference of dextran alone as a material to be connected. The last line of column 7 of the patent indicates that dextran sulfate is a carbohydrate useful for chromatography media. The patent further contains a discussion of using dextran sulfate as a chemical specie in combination with a coupling compound to bring those materials into "association permitting ionic attraction between them to pre-orient the chemical

specie and the polymeric coupling compound with respect to each other before they are covalently bonded"; see column 9, line 66 to column 10, line 4. Patent Example 12 (see columns 16 and 17) shows dextran sulfate (not dextran) co-immobilized onto polystyrene beads using a photoderivatized polyacrylamide made in Example 5 and a polyionic polymeric coupling compound made in Example 11. The connecting agent (the coupling compound) unquestionably is organic polymer based. Proteins, modified or not, are not disclosed as coupling compounds. (The Examiner acknowledges in the September 29, 2003 Advisory Action that Swan et al. '056 does not teach the use of a protein. Lacking such disclosure, why would one search out disclosure of a protein, let alone disclosure of T-aminodextran?)

The Examiner asserts in the first paragraph on page 4 of the Office Action that Swan et al. '056 discloses dextran as the polymer from which the "coupling compound" is derived. Dextran is not the "coupling compound" in the context of the present invention. The lack of Swan et al. '056's pertinence to the present invention is proven by the Examiner's remark. Swan et al. '056 is not related to the present invention.

Hubbell et al. '914 discloses ways to form biocompatible membranes around biological materials by the use of photopolymerized water-soluble molecules. For purposes of polymerization, the invention described in the reference uses materials called "macromers," which are described in detail at column 11 of the document. Listed as a macromer example are "ethylenically unsaturated derivatives" of dextran. Thus, the reference itself has no awareness, discussion, recognition, or understanding of using dextran itself (or T-aminodextran) as a material which is to be linked to a substrate. The only way in which dextran can be utilized for purposes of the Hubbell et al. '914 invention is as the central portion of an ethylenically unsaturated derivative of dextran. The reference also contains no mention of a protein, modified or otherwise, as a linker and the reference is believed not properly applicable here. Not only is the dextran used in Hubbell et al. '914 not dextran itself (rather the dextran is the central portion of an ethylenically unsaturated derivative of dextran), the Hubbell et al. '914 "dextran" is a "coupling component" rather than a material to be coupled. See the similar remarks above regarding the Examiner's discussion of

dextran as a "coupling component" in the Swan et al. '056 invention. (The Examiner acknowledges in the Advisory Action that Hubbell et al. '914 teaches derivatives of dextran rather than dextran itself. Moreover, the subsequent change to claim 3 takes the claimed subject matter even further away from the Hubbell et al. '914 teachings.)

The deficiencies of Swan et al. '056 and Hubbell et al. '914 are not overcome by the disclosure in Chai-Gao et al. '802. While the reference does refer to BSA and TRIMID, there is no example, let alone discussion in the reference, of using TRIMID-modified proteins and particularly TRIMID-modified aminodextran as a co-immobilizer for dextran to a substrate. Chai-Gao et al. '802 has no mention of dextran and there is no proper reason to combine these references. (The Examiner remarked in the Advisory Action that Chai-Gao et al. '802 was cited merely to show a TRIMID-protein used in immobilization. The references must provide the motivation for their combination. Here, those references are so unrelated that one cannot properly combine them. Hindsight rationale is not proper.)

Applicants further respectfully submit that the rationale advanced in the paragraph bridging pages 4 and 5 of the Office Action establishes that the Examiner has used hindsight to try to justify the rejection. There is no "reasonable expectation of success" because there is no proper reason drawn from the references themselves for their combination. And, even when combined, the present invention does not result. The rejection should be withdrawn.

The rejection of claims 3 and 6 to 15 under 35 USC 103 as unpatentable over Swan et al. '056 or Hubbell et al. '914 in view of Wessa et al. WO '631 is also respectfully traversed.

The deficiencies of Swan et al. '056 and Hubbell et al. '914 have been discussed above and will not be repeated here. Applicants respectfully submit that Wessa et al. WO '631 does not make up for the deficiencies of the primary references. The secondary reference here describes a prior art technique involving TRIMID and T-BSA but the reference in no proper fashion teaches or suggests the subject matter of the claims. The rejection should be withdrawn as well.

Wessa et al. WO '631, which as the instant case has Dr. Hans Sigrist as a joint inventor, describes a prior art technique of covalently-linked (therefore not diffusible) carbene mediated immobilization of a biomolecule to a polyimide. (The Examiner states in the Advisory Action that Wessa et al. WO '631 was cited merely to show a protein. More is required to make the rejection a proper one. The art has to provide some reason for its combination.) The discussion taken with either Swan et al. '056 or Hubbell et al. '914 does not direct the person of ordinary skill in the art to the invention claimed here.

Applicants respectfully submit that the statements in the paragraph bridging pages 5 and 6 of the Office Action establish that hindsight was used in this rejection as well. The rationales advanced come not from the cited art but from an attempt to justify a rejection improperly made.

In view of the foregoing remarks, it is respectfully submitted that the claims patentably define over the cited art and comply with the formal requirements of the Patent Code.

An early allowance of claims 3 and 6 to 15 is earnestly solicited.

The Examiner is requested to telephone the undersigned if changes are required in the case prior to allowance.

Respectfully submitted,

PARKHURST & WENDEL, L.L.P.

May 24, 2004
Date

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CAW/ch
Enclosure:
Analytical Chemistry article

Attorney Docket No.: CSEM:065

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